December 18, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

OPP #0014

A Portion of Document #14 (Page #2 and #62) Have Been Claimed Confidential. Request for the Confidential Portion of this Document Will be Filled under the Provisions of the Freedom Of Information Act.

14/OPP #

SM

Jellinek, Schwartz & Connolly, Inc.

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AN IT COMPANY

JSC

Hand Delivered

November 12, 1998

Ms. Emily Mitchell
Case Manager
Reregistration Branch I
Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall 2, Room 657
1921 Jefferson Davis Highway
Arlington, VA 22202

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Dear Ms. Mitchell:

This letter is submitted on behalf of Cheminova Agro A/S (Cheminova) and concerns the Office of Pesticide Programs' preliminary environmental fate and ecotoxicology risk assessments that were included in the draft Environmental Fate and Effects Division Reregistration Eligibility Decision (RED) chapter for methyl parathion. These comments are submitted in response to an October 28, 1998, letter from Arnold Layne (Chief, EPA's Reregistration Branch I).

Three copies of the following data and information (all formatted per PR Notice 86-5) are being submitted:

VOLUME #	GUIDELINE #	MRID	TITLE
I	not applicable		Comments on EPA's Methyl Parathion Draft Environmental Fate and Effects Division Chapter of the Reregistration Eligibility Decision Document (with the following attachment) Attachment A: **CONFIDENTIAL ATTACHMENT** - This attachment has sales information on methyl parathion and has been removed from the releasable part of this document.
II	163-3		Fritz, R. (1992) "Determination of the Volatilization of Parathion-Methyl in a Field Experiment" Bayer AG, Agrochemicals Division, Report No. PF-3774

As requested, we are also enclosing an electronic copy of our comments (Volume I from the table above).

We have reviewed the draft Agency document for possible Confidential Business Information (CBI). [redacted]

Likewise, we have considered our own comments and the other documents we are submitting (identified above) for possible CBI. The documents we are submitting have all been formatted according to PR Notice 86-5 (in anticipation of receiving an MRID number for each document) and, thus, any CBI has been identified and handled according to the PR Notice.

Further, throughout our comments we have identified additional testing we have planned or have underway. As soon as we have completion dates, we will inform the Agency of our target submission dates for these studies.

Lastly, on pages 9-11 of our comments, we have identified the errors in EPA's documents that should be corrected before the documents are released for public comment.

We appreciate the effort the Agency staff has put into preparing this draft RED chapter and we welcome the opportunity to comment on it. We request a reasonable period of time to review the methyl parathion docket prior to its public release. We consider this submission a continuation of our dialogue with the Agency on the reregistration of methyl parathion and believe the next best step may be a meeting with you and the other methyl parathion team members to discuss our comments. Please do not hesitate to call me (703-312-8520) if you have any comments about our comments or the other documents in this submission.

Sincerely,

Diane Allemang

Diane Allemang
Jellinek, Schwartz & Connolly, Inc.
Authorized Representative of
Cheminova Agro A/S

Enclosures

c: David Menotti, Shaw Pittman
Don O'Shaughnessy, Cheminova Inc.
Jon Weis, Cheminova Agro A/S

2962

Report Title

Evaluation of the Environmental Fate and Effects Division's
Draft Reregistration Eligibility Decision Chapter for Methyl Parathion

Data Requirements

Not Applicable

Author(s)

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Performing Laboratory

Not Applicable

Report Completion Date

November 12, 1998

Submitter

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Report Number

Not Applicable

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA ' 10 has been removed to a confidential attachment, and is cited by cross-reference number in the body of the study.

Company: Cheminova Agro A/S

Company Agent: Jon Weis

Title: Manager, Patents and Registration

Signature: ________________________ Date: ________________

These data are the property of Cheminova Agro A/S and as such, are considered to be confidential for all purposes other than compliance with FIFRA ' 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality which may exist under any other statute or in any other country.

CERTIFICATION OF GOOD LABORATORY PRACTICE

This report is a response to EPA's draft Environmental Fate and Effects Division Chapter of the Reregistration Eligibility Decision Document for methyl parathion. As such, Good Laboratory Practice Standards (40 CFR Part 160) are not applicable to this submission.

Submitter: ________________________ Date: ____________________

Diane Allemang
Jellinek, Schwartz & Connolly, Inc.
Authorized Representative for
Cheminova Agro A/S

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Attachment

CONFIDENTIAL ATTACHMENT – This attachment has sales information on methyl parathion and has been removed from the releasable part of this document.

EXECUTIVE SUMMARY

Cheminova Agro A/S (Cheminova) is submitting these comments on EPA's Environmental Fate and Effects Division's (EFED) draft Reregistration Eligibility Decision (RED) chapter (dated October 27, 1998). In light of the extremely short review and comment period EPA allowed (i.e., only 15 days), this response should be considered a preliminary assessment. The assessment includes a review of EPA's statements about methyl parathion usage, EFED's suggested new study requirements, environmental fate assessment, and ecological risk assessment.

USE PATTERNS

Methyl parathion is a broad spectrum insecticide for use on a variety of agricultural crops, and it has been used worldwide for more than 40 years. Until recently, Cheminova was the only registrant for technical methyl parathion. Cheminova's review of EFED's description of the usage rates and patterns for this insecticide has identified several important errors and omissions. These issues are discussed in Sections II and III of this document.

STUDY REQUIREMENTS

The EFED review states that most of the environmental fate data requirements for methyl parathion have been satisfied, but lists five specific data gaps and one general comment on the adequacy of data on the formation of methyl paraoxon in the environment.

For the adsorption/desorption study (Guideline 163-1), Cheminova agrees to repeat the study when a formal Data Call-In (DCI) is issued. For the other studies, Cheminova has supplied or will provide a rebuttal to the EFED comments.

ENVIRONMENTAL FATE ASSESSMENT

Cheminova reviewed the assumptions that EFED made for its calculation of estimated environmental concentrations (EECs) in surface water bodies. Cheminova has identified a variety of environmental fate parameter assumptions that it believes are inappropriate, including EFED's choice of the following parameters:

- Soil Adsorption Coefficient,
- Aerobic Soil Metabolism,
- Foliar Dissipation, and
- Bacterial Degradation.

In particular, the soil adsorption coefficient used by EFED is likely an order of magnitude lower than the true value. Because this is the most sensitive variable in the run-off model used by EPA, it is imperative that this value be corrected. (Cheminova agrees to conduct a new study to measure this value when a formal DCI is made.)

Cheminova also reviewed EFED's discussion of the available groundwater and surface water monitoring. Cheminova believes that because there are no detectable measurements in the United States Geological Services (USGS) National Water Quality Assessment Program (NAQWA) database for groundwater (the EFED document states incorrectly that there were detections), EPA's decision requiring a new groundwater monitoring study is inappropriate. Also, Cheminova believes that it is important to prominently note to readers of the EFED document that the available water monitoring data suggest that EFED's surface EECs are several orders of magnitude too high.

ECOLOGICAL RISK ASSESSMENT

Cheminova provides extensive comments on the ecological risk assessment. Key points from this discussion include the following:

- Cheminova disagrees with EFED's claims of high degrees of certainty that labeled uses of methyl parathion will result in adverse acute and/or chronic effects on birds, small mammals, and aquatic invertebrates because of the numerous uncertainties inherent in EFED's risk analyses. In its preliminary review of EFED's draft RED, Cheminova has identified misstatements and/or improper use of both exposure and toxicity data by EFED that introduce orders of magnitude errors in calculated risk quotients.

- All of EFED's risk analyses and conclusions are based on maximum application rate scenarios that EFED admits do not reflect the actual use of methyl parathion on the crops that were evaluated. However, in the ecological risk sections of its draft RED chapter, EFED suggests that its analyses reflect actual use of methyl parathion, when EFED's analyses actually represent completely hypothetical use scenarios. Much more relevant risk analyses should be conducted based on realistic use information if EFED's intention is to assess the potential risks associated with actual use of the product.

- EFED neglects to present the underlying assumptions and limitations of its risk analysis methodologies, as well as the numerous uncertainties arising from those methodologies. Clearly presenting the assumptions and limitations of risk analysis procedures is fundamental to drawing proper conclusions from those analyses.

I. INTRODUCTION

Cheminova Agro A/S (Cheminova) respectfully submits these comments on the Environmental Fate and Effects Division's (EFED) draft Reregistration Eligibility Decision (RED) chapter for methyl parathion dated October 27, 1998. (Please note that Cheminova was provided only 15 days to review and comment on the draft EFED chapter.) These comments provide EFED with additional information about methyl parathion and its supported use patterns, as well as Cheminova's preliminary assessment of EFED's risk assessment. These comments are organized by the major topics discussed in the EFED document, including (1) supported usage patterns, (2) environmental fate, and (3) ecological toxicity. As requested, to allow EFED to quickly access the mistakes and areas requiring clarification in the document, a separate section summarizes the errors found by Cheminova.

Methyl parathion, a broad spectrum insecticide for use on a variety of agricultural crops, has been used worldwide for more than 40 years. Cheminova is the major producer of technical methyl parathion. Elf Atochem North America, Inc. (Elf Atochem) is the sole producer of the encapsulated formulation of methyl parathion (Mcap). Cheminova has a long track record of compliance with all federal testing and labeling requirements for methyl parathion and its other pesticide products. During the past several years, Cheminova has conducted and submitted numerous studies to fully characterize the toxicity of methyl parathion. All of these studies have been submitted to the Office of Pesticide Programs (OPP), in accordance with EPA's schedule for data submission, to support the registration of Cheminova's technical methyl parathion. Further, Cheminova worked with the Agency to minimize potential risk posed by the use of methyl parathion. In this regard, Cheminova fully cooperated with EPA's initiative to reduce the chance of illegal misuse by agreeing to and implementing formulation and packaging changes.

Section II of this report lists the errors found in Cheminova's analysis of the EFED document. Section III provides clarification of the supported uses of methyl parathion. Section IV provides a response to EFED's study requirement recommendations. Section V provides a detailed review of the studies and modeling used to assess the environmental fate of methyl parathion. Section VI provides a detailed review of EFED's assessment of the ecological toxicity and risk of methyl parathion. Section VII contains concluding remarks. Section VIII lists the references cited in this report.

II. COMMENTS ON ERRORS

In the October 28, 1998, cover letter from Arnold Layne (Chief, Reregistration Branch 1, Special Review and Reregistration Division [SRRD]) that accompanied EPA's draft EFED chapter for the methyl parathion RED, the Agency requested that Cheminova limit its comments in the 30-day period (15 days for this particular response) to comments on errors including, but not limited to, "mathematical, computational, typographic, or other similar errors." Listed below are the errors of this sort that Cheminova has identified within the draft EFED chapter. Cheminova believes that there are many more "errors" that do not fit EPA's restrictive definition, such as errors in applicability of data and flaws in data analysis. These types of errors are identified later in this document in relevant sections.

A. USE PATTERNS FOR METHYL PARATHION

1. On page 38 of the EFED chapter, EPA states that if "any potential registrant requests the use (of methyl parathion) on these crops (apricot, artichoke, beets, cucumber, gooseberry, kohlrabi, rutabaga, safflower, and tobacco), a new risk assessment will be needed" because these uses were not included in EFED's risk assessments. Cheminova notes that it is supporting the use of the emulsifiable concentrate (EC) formulation of methyl parathion on artichokes. The other uses will not be supported for reregistration unless others (e.g., other registrants, IR-4) are willing to submit their own data to support such registrations.

2. In the last sentence of the second paragraph under the field volatility heading on page 8, EPA states that a USGS review reported methyl parathion in air samples associated with the use of methyl parathion in tobacco production. Because methyl parathion is not being supported for the use on tobacco, Cheminova believes the reference to tobacco is not relevant for this risk assessment and should be deleted.

3. The tables on pages 47, 48, 51, 56, 58, 60, 62, and 67 list sorghum as one of the crops included in EFED's risk assessment. Cheminova is not supporting the use of methyl parathion on sorghum. Cheminova is not aware of any registrant interested in supporting this use.

4. The tables on pages 50 and 51 list ornamental herbs and uncultivated agricultural lands as uses included in EFED's risk assessments. Cheminova is not supporting these uses for reregistration.

5. The tables on pages 62 and 67 state that peaches are included as a surrogate for citrus. Methyl parathion is not used on any citrus crop. This reference should be deleted.

6. In the paragraph on page 74 under the heading "Freshwater Aquatic Invertebrates," EFED references modeling done on nonagricultural lands. The use of methyl parathion on nonagricultural lands is not being supported in reregistration. Reference to this use should be deleted.

7. On page 1 of the October 27, 1998, memorandum to Emily Mitchell (Chemical Review Manager, SRRD) from Kevin Costello (Task Leader, EFED), EPA states that methyl parathion is registered for use on 48 crops. Cheminova believes that methyl parathion is registered for use on a total of 50 crops. A list of the supported crops for the EC and Mcap formulations is provided later in this document. These are the only two formulations that will be supported in reregistration.

8. On page 2 of the October 27, 1998, memorandum to Emily Mitchell, EFED states "Ten seasonal applications are permissible at a minimum 7 day interval" for cotton. Actually, a 3-day interval is permitted, as EFED states in other parts of the document.

9. In the section titled "Introduction and Use Characterization," EPA states that Cheminova produces all of the technical methyl parathion sold in the United States. This statement is not true. In 1998, EPA granted a registration to Griffin Corporation to sell technical methyl parathion in the United States.

B. ENVIRONMENTAL FATE ASSESSMENT

1. For the Pesticide Root Zone Model (PRZM), EFED used different values for the adsorbed and aqueous aerobic soil half-lives in different scenarios. Because EFED only provides data to support one value, Cheminova believes that a mistake was made when EFED created its PRZM input files and that the same value should have been used for the adsorbed and aqueous aerobic soil half-lives in all of the scenarios.

2. EPA mistakenly suggests on page 25 that the maximum detectable concentration in NAWQA for groundwater was 0.062 ppb. In fact, there were no detectable concentrations. The highest detection limit that was reported was less than 0.062 ppb.

3. For the PRZM/EXAMS modeling, EFED assumes no foliar dissipation. However, in the ecological risk section on page 40, EFED quotes a review article on methyl parathion foliar dissipation and states that the upper 90th percentile confidence limit value for the foliar half-life is 2.4 days.

C. ECOLOGICAL RISK CHARACTERIZATION

1. On page 30, the sentence before the Avian Acute Dermal Toxicity table is an incomplete sentence.

2. Neither *Kirschneria subcapitatum* or *Anabaena flos-aquae* are diatoms as stated by EFED on page 38. In addition, *Kirschneria subcapitatum* is not a marine species.

III. SUPPORTED USE PATTERNS

Based on its review of the issues raised in EFED's draft RED chapter, Cheminova believes that there are a number of misunderstandings regarding how methyl parathion is used in the United States. Cheminova believes that clarification of the uses and use patterns that it or others will support in the reregistration process will eliminate many of the concerns expressed by the Agency in its preliminary risk assessments (e.g., by eliminating problematic uses or use patterns).

A. USAGE OF METHYL PARATHION IN THE UNITED STATES

In its draft RED chapter, EFED states that approximately nine million pounds of methyl parathion are used annually in the U.S. Cheminova believes this amount is much lower.

Since 1994, the reduction of use of methyl parathion has been a clear trend. A number of factors are related to this decrease, including the elimination of the major cotton pests by the Boll Weevil Eradication Programs, the decreased dependence on chemicals as a sole means of controlling agricultural pests (i.e., use of integrated pest management programs), and the growing popularity of crops engineered to produce natural toxins as a defense against target pests (i.e., *bacillus thurengiensis* in cotton). In addition, the recall and packaging requirements of the December 1996 Agreement with EPA has resulted in a major reduction in sales of the EC formulations (see Table A-1).

B. SUPPORTED FOOD/FEED USES AND USE PATTERNS

Methyl parathion is a broad spectrum insecticide that is applied as a foliar spray to a variety of agricultural crops, including fruits, vegetables, and grains. Methyl parathion has no registered domestic, residential, or indoor uses. There are only two formulations that are being supported for reregistration: emulsifiable concentrate (EC) and microencapsulated (Mcap) formulations. Tables 1 and 2 list the crops supported by Cheminova and Elf Atochem for the EC and Mcap formulations, respectively.

Recommended label rates for the EC and Mcap formulations range from 0.125 pounds of active ingredient (lb a.i.) per acre to 3.0 lbs a.i. per acre. The labeled maximum use patterns for EC and Mcap formulations for the supported crops are summarized in Tables 3 and 4, respectively.

For leafy vegetables, small grains, and other vegetable applications, methyl parathion is typically applied at rates ranging from 0.25 lb a.i. per acre to 1.0 lb a.i. per acre. The typical use patterns for the supported crops for the EC and Mcap formulations are summarized in Tables 5 and 6, respectively.

C. SUPPORTED NONFOOD/FEED USES AND USE PATTERNS

Cheminova's current technical label allows the use of methyl parathion for the following terrestrial, nondomestic, and nonfood uses:

- jojoba (special local need),
- guayule (special local need),
- field grown ornamental flowering plants,
- chrysanthemums,
- daisies,
- marigolds,
- nursery stock,
- nonagricultural lands, and
- wastelands.

Although these uses are currently allowed by Cheminova's technical label, Cheminova will not continue to support them. These uses are not included on Cheminova's end-use labels.

Cheminova also is not supporting the use of methyl parathion for these purposes:

- to control pests in and around nurseries and nursery plantings,
- for public health control (mosquitoes and rodents),
- for regulatory pest control (government-led control of infestations or for quarantine purposes),
- for landscape maintenance,
- on Christmas tree plantations, or
- on pine forests.

Cheminova urges the Agency to cancel any existing registrations of such uses.

D. CHEMINOVA'S COMMENTS ON THE USES INCLUDED IN EFED'S RISK ASSESSMENTS

Outlined below are specific comments from Cheminova regarding the uses of methyl parathion that were included in EPA's risk assessments.

1. On page 1 of the October 27, 1998, memorandum to Emily Mitchell (Chemical Review Manager, Special Review and Reregistration Division) from Kevin Costello (Task Leader, EFED), EPA states that methyl parathion is registered for use on 48 crops. Cheminova believes that methyl parathion is registered for use on a total of 50 crops. Tables 1 and 2 identify the supported crops for the EC and

Mcap formulations, respectively. These are the only two formulations that will be supported for reregistration.

2. On page 6 of the October 27, 1998, memorandum, EFED provides suggestions for risk reduction, including that registrants should consider significant reductions in the maximum use rate and the number of applications for most uses. Cheminova is conducting higher tiered risk assessments for the EC and Mcap formulations using maximum supported use patterns (Tables 3 and 4) and the typical use patterns (Tables 5 and 6) for these formulations. Preliminary results of this work indicate that the risk is significantly lower than the EECs (see Section V). Cheminova is continuing to refine the risk assessments and will submit the results to EPA when the work is completed during the 60-day public comment period.

3. In the section titled "Introduction and Use Characterization," EFED states that Cheminova produces all of the technical methyl parathion sold in the United States. This statement is no longer true. In 1998, EPA granted a registration to Griffin Corporation to sell technical methyl parathion in the United States.

1. On page 38 of the EFED chapter, EPA states that the "addition of uses, such as public health mosquito control, would similarly require a new risk assessment." Cheminova will not support the use of methyl parathion to control mosquitoes and urges the Agency to not allow such a use.

E. COMMENTS ON USES SELECTED BY EFED FOR PRZM AND EXAMS MODELING

EFED modeled the following nine crops: cotton, corn, alfalfa, peaches, potatoes, pecans, cherries, grapes, and sweet potatoes. Cheminova's evaluation of each scenario is discussed below.

1. Cotton: EFED modeled the use of the EC formulation on cotton to represent a mid-height field crop. EFED modeled cotton using the maximum labeled rate of 3.0 lb a.i. per acre applied 10 times per year at 3-day intervals. According to usage estimates compiled by the National Center for Food and Agricultural Policy (NCFAP), more than 50% of the usage of methyl parathion is on cotton (see Table 7). Cheminova agrees with EPA's statement that methyl parathion is rarely applied at the maximum use rates listed on the label. According to conversations with growers, Cheminova believes methyl parathion is typically applied no more three times per year at a maximum rate of 2.0 lb a.i. per acre with a minimum 7-day interval between applications.

2. Corn: EPA modeled the use of the Mcap formulation on corn to represent a tall field crop. According to usage estimates compiled by the NCFAP, usage of methyl parathion on this crop is second only to the usage on cotton (see Table 7).

3. Alfalfa: EPA apparently modeled the use of the Mcap formulation on alfalfa to represent a low-growing field crop. Because Elf Atochem is not supporting the use of the Mcap formulation on alfalfa, this risk assessment is not valid. A new risk assessment should be conducted with the EC formulation. According to usage estimates compiled by the NCFAP, the usage of methyl parathion on alfalfa is third behind only cotton and corn (see Table 7).

4. Peaches (with surrogation to nectarines and plums): EPA modeled the use of methyl parathion on peaches to represent an orchard crop. Cheminova assumes that EPA modeled the use of the Mcap formulation on peaches because Cheminova is not supporting the use of the EC formulation on peaches. EPA should specify which formulation was modeled. Cheminova notes that the usage of methyl parathion on apples (177,141 lb a.i./crop/year) is greater than the use on peaches (93,511 lb a.i./crop/year). EPA should specify why peaches were chosen over apples for the modeling. According to useage estimates compiled by the NCFAP, apples and/or peaches are the two top orchard crops on which methyl parathion is used; however, peaches only represent only about 1.6% of methyl parathion use (see Table 7).

5. Potatoes (with surrogation to cabbage, mustard, and tomatoes): EPA modeled the use of methyl parathion on potatoes to represent a low-growing field crop. EPA should specify which formulation was modeled because both the EC and Mcap formulations are used on this crop. According to usage estimates compiled by the NCFAP, potatoes represent about 1.2% of methyl parathion use (see Table 7).

6. Pecans (with surrogation to almonds): EPA modeled the use of methyl parathion on pecans to represent a grove crop. Cheminova assumes that EPA modeled the use of the Mcap formulation on pecans since Cheminova is not supporting the use of the EC formulation on this crop. EPA should specify which formulation was modeled. Of the supported grove crops (almonds and walnuts are also supported), the use of methyl parathion is largest on pecans; however, this use represents less than 1% of methyl parathion use (see Table 7).

7. Cherries (with surrogation to prunes): EPA modeled the use of methyl parathion on cherries to represent an orchard crop. Cheminova assumes that EPA modeled the use of the Mcap formulation on cherries since Cheminova is not supporting the use of the EC formulation on this crop. EPA should specify

which formulation was modeled. According to useage estimates compiled by the NCFAP, the use of methyl parathion on this crop represents 0.2% of the total usage of methyl parathion in the U.S.; thus, Cheminova does not believe this use is of any national significance.

8. Grapes: EPA modeled the use of methyl parathion on grapes to represent a the use of methyl parathion in a vineyard. Only the Mcap formulation is registered for use on grapes; therefore, EPA should specify whether it modeled the Mcap formulation for this use. According to useage estimates compiled by the NCFAP, the use of methyl parathion on this crop represents 0.2% of the total usage on methyl parathion in the U.S.; consequently, Cheminova does not believe this use is of any national significance.

9. Sweet potatoes: EPA modeled the use of methyl parathion on sweet potatoes to represent a low-growing field crop. Only the Mcap formulation is registered for use on sweet potatoes; therefore, EPA should specify whether it modeled the Mcap formulation for this use. Cheminova is unclear why EFED chose to model this use because it is only a Section 24(c) special local needs registration held by Elf Atochem for the Mcap formulation. Cheminova does not believe this use is of any national significance.

Table A-1. Sales of Technical Methyl Parathion Used to Formulate EC Products.

Cross Reference Number _1_	This cross reference number noted as a place-holder on this page and is used in place of the following whole page at the indicated volume and page reference.

This deleted page is in CONFIDENTIAL ATTACHMENT A.

Table 1. Methyl Parathion: Supported Food/Feed Uses for EC Formulations.

Root and Tuber Vegetables	Legume Vegetables
Carrots	Beans, succulent
Potatoes	Beans, dried
Sugar beets	Lima beans
Turnips	Peas, succulent
	Peas, dried
Bulb Vegetables	Soybeans
Onions	
	Fruiting Vegetables
Leafy Vegetables	Peppers[1]
Celery	
Lettuce (head and leaf)	**Miscellaneous Crops**
Spinach	Artichokes (globe)
	Cotton
Brassica Leafy Vegetables	Hops[1]
Broccoli	Rapeseed (canola)
Brussels sprouts	Sunflowers
Cabbage	
Cauliflower	**Cereal Grains** [2]
Collards	Barley
Kale	Corn, field
Mustard greens	Corn, sweet
	Oats
Cucurbit Vegetables	Rice
Melons[1]	Rye
	Wheat
Non grass Animal Feeds	
Alfalfa[3]	**Grass forage, fodder, and hay**
	Grasses

Notes:

1. This is a new use supported by IR-4. Cheminova does not intend to submit data to support this use.

2. Cheminova will support a cereal grain crop group tolerance excluding sorghum. Cheminova will not support the use of methyl parathion on sorghum.

3. Cheminova will not support the use for alfalfa grown for seed.

Table 2. Methyl Parathion: Supported Food/Feed Uses for the Mcap Formulation.

Root and Tuber Vegetables	**Pome Fruits**
Potatoes	Apples
Sweet potatoes*	Pears
Bulb Vegetables	**Fruiting Vegetables**
Onions	Tomatoes
Stone Fruits	**Tree Nuts**
Cherries	Almonds
Nectarines	Pecans
Peaches	Walnuts
Plums/prunes	
Legume Vegetables	**Cereal Grains**
Beans, dried	Wheat
Beans, succulent	Oats
Lentils	Barley
Peas	Corn (field and sweet)
Soybeans	Rice
	Rye
Miscellaneous Crops	
Cotton	
Grapes	
Peanuts	

*This is a 24(c) registration only.

Table 3. Methyl Parathion: Maximum Supported Use Patterns for EC Formulations.

Crop	Maximum Single Application Rate (1bs a.i./A)	Maximum Number of Applications per Year	Maximum Amount Applied per Year (lbs a.i./A) [a]	Minimum Application Interval (days)	Minimum Pre-harvest Interval (days)
Root and Tuber Vegetables					
Carrots	1.0	6	6.0	7	15
Potatoes	1.5	6	9.0	7	5
Sugar beets	0.375	6	2.25	7	20
Turnips	0.75	2	1.5	7	7
Bulb Vegetables					
Onions	1.0	6	6.0	7	15
Leafy Vegetables					
Celery	1.0	2	2.0	14	15
Lettuce (head and leaf)	1.0	6	6.0	7	15
Spinach	1.0	6	6.0	7	15
Brassica Leafy Vegetables					
Broccoli	1.5	6	7.0	7	7
Brussels sprouts [b]	1.5	6	7.0	7	7
Cabbage	1.5	6	8.0	7	10-21 [c]
Cauliflower [b]	1.5	7	7.0	7	7
Collards [d]	1.5	6	8.0	7	10-21 [c]
Kale	1.5	6	8.0	7	10-21 [c]
Mustard greens	1.5	6	8.0	7	10-21 [c]
Legume Vegetables					
Beans, succulent	1.5	6	9.0	7	15
Beans, dried	1.5	6	9.0	7	15
Lima beans	1.5	6	9.0	7	21
Peas, succulent	1.0	6	6.0	7	10-15 [e]
Peas, dried	1.0	6	6.0	7	10-15 [e]
Soybeans [f]	0.5	2	1.0	5	20
Cucurbit Vegetables					
Melons [g]	0.5	5	2.5	7	7

Fruiting Vegetables					
Peppers [g]	1.0	5	5.0	7	15

Table 3. Methyl Parathion: Maximum Supported Use Patterns for EC Formulations *(continued)*.

Crop	Maximum Single Application Rate (lbs a.i./A)	Maximum Number of Applications per Year	Maximum Amount Applied per Year (lbs a.i./A) [1]	Minimum Application Interval (days)	Minimum Pre-harvest Interval (days)
Cereal Grains [h]					
Barley [i]	1.25	6	6.5	7	15
Corn, field	1.0	6	6.0	7	12
Corn, sweet	0.5	6	3.0	3	3
Oats [i]	1.25	6	6.5	7	15
Rice	0.75	6	4.5	7	15
Rye [i]	1.25	6	6.5	7	15
Wheat	1.25	6	6.5	7	15
Miscellaneous Crops					
Artichokes (globe)	1.0	4	4.0	7	7
Cotton	3.0	10	26.0	3	7
Hops [g]	1.0	3	3.0	7	15
Rapeseed (canola)	1.0	4	3.0	7	28
Sunflowers	1.0	3	3.0	7	30
Non-Grass Animal Feeds					
Alfalfa	1.0	2/cutting	10.0	4	15
Grass, Forage, Fodder, and Hay					
Grass	0.75	2/cutting	3.0	7	0

a The maximum amounts of methyl parathion allowed to be applied per season reported in this table are based on the maximum amount applied during the conduct of Cheminova's magnitude of the residue field trials; these amounts are not the result of multiplying the maximum single application rate and the maximum number of applications made. In Cheminova's field trials, multiple applications were applied at various rates up to the maximum amounts reported in this table.

b No data have been submitted to support this use. According to the November 24, 1992, Methyl Parathion Residue Chemistry Registration Standard Update, data can be translated from broccoli to support this use. The use pattern specified in this table is based on the use pattern for broccoli.

c The preharvest interval of 10 days applies if the final application is less than 1.0 lb a.i./acre. A 21-day preharvest interval applies if the final application is 1.0 lb a.i./acre or more.

d No data have been submitted to support this use. According to the November 24, 1992, Methyl Parathion Residue Chemistry Registration Standard Update, data can be translated from mustard greens to support this use. The use pattern specified in this table is based on the use pattern for mustard greens.

e The preharvest interval of 10 days applies if the final application is less than 1.0 lb a.i./acre. A 15-day preharvest interval applies if the final application is 1.0 lb a.i./acre or more.

f Cheminova is supporting the use of the EC formulation of methyl parathion on this crop; however, Cheminova will not support the use on forage and hay. Cheminova plans to add a feeding/grazing restriction to its end-use labels to prohibit use on forage and hay.

g This is a new use supported by IR-4. Cheminova does not intend to submit any data to support this use. The use pattern reported here is the use pattern proposed by IR-4.

h Cheminova will support a cereal grain crop group tolerance, but it will not support the use of the methyl parathion EC formulations on sorghum.

i Cheminova is supporting the use of the EC formulation of methyl parathion on barley, oats, and rye. Wheat data were translated to support these uses. The use patterns stated in this table for these crops are the same as that tested for wheat.

Table 4. Methyl Parathion: Maximum Supported Use Patterns for the Mcap Formulation.

Crop	Maximum Single Application Rate (lbs a.i./A)	Maximum Number of Applications per Year	Maximum Amount Applied per Year (lbs a.i./A)	Minimum Application Interval (days)	Minimum Pre-harvest Interval (days)
Root and Tuber Vegetables					
Potatoes	0.5	6	9.0	7	5
Sweet potatoes	0.75	8	6.0	7	5
Bulb Vegetables					
Onions	1.0	6	6.0	7	15
Legume Vegetables					
Beans, dried	1.0	6	6	3	15
Beans, succulent	1.0	6	6	7	7
Lentils	0.5	3	1.5	11	14
Peas	0.5	2	1.0	7	15
Soybean	1.0	2	2.0	7	30
Pome Fruits					
Apples	2.0	5	9.0	7	21
Pears	2.0	5	9.0	7	21
Stone Fruits					
Cherries	1.5	6	9.0	7	15
Nectarines	2.0	6	12.0	7	30
Peaches	2.0	6	12.0	7	30
Plums/prunes	1.5	4	6.0	7	15
Fruiting Vegetables					
Tomatoes	1.0	5	5.0	6	15
Tree Nuts					
Almonds	2.0	6	12.0	21	24
Pecans	2.0	8	16.0	13	15
Walnuts	2.0	4	8.0	21	14
Cereal Grains					
Barley	0.75	3	2.25	7	14
Corn (field and sweet)	1.0	5	5.0	14	12
Oats	0.75	3	2.25	7	14

Rice	0.75	6	4.5	21	15
Rye	0.75	3	2.25	7	14
Wheat	0.75	3	2.25	7	14
Miscellaneous Crops					
Cotton	1.0	8	8.0	5	14
Grapes	1.0	2	2.0	7	28
Peanuts	1.0	4	4.0	14	15

Table 5. Methyl Parathion: Typical Use Patterns for EC Formulations.

Crop	Typical Single Application Rate (lbs a.i./A)	Typical Number of Applications per Year	Typical Amount Applied per Year (lbs a.i./A) [a]	Typical Application Interval (days)	Typical Pre-harvest Interval (days)
Root and Tuber Vegetables					
Carrots	1.0	2	2.0	7-10	15
Potatoes	1.5	3	4.5	7-10	6
Sugar beets	0.5	2	1.0	7-10	20
Turnips	0.75	2	1.5	7-10	10
Bulb Vegetables					
Onions	0.5	2	1.0	7-10	15
Leafy Vegetables					
Celery	1.0	2	2.0	10-14	15
Lettuce	1.0	1	1.0	7	15
Spinach	1.0	2	2.0	7-10	15
Brassica Leafy Vegetables					
Broccoli	1.5	2	3.0	7-10	7
Brussels sprouts [b]	1.5	2	3.0	7-10	7
Cabbage	1.5	2	3.0	7-10	10-21 [c]
Cauliflower [b]	1.5	2	3.0	7-10	7
Collards [d]	1.5	2	3.0	7-10	10-21 [c]
Kale	1.5	2	3.0	7-10	10-21 [c]
Mustard greens	1.5	2	3.0	7-10	10-21 [c]
Legume Vegetables					
Beans, succulent	1.5	2	3.0	7-10	15
Beans, dried	1.5	2	3.0	7-10	15
Peas, succulent	1.0	3	3.0	7-10	10-21 [e]
Peas, dried	1.0	3	3.0	7-10	10-21 [e]
Lima beans	1.5	2	3.0	7-10	15
Soybeans [f]	0.5	2	1.0	5-7	20
Cereal Grains [g]					
Barley [h]	0.75	2	1.5	7-10	15
Corn, field	0.5	2	1.0	5-7	12
Corn, sweet	0.5	2	1.0	5-7	12

Oats [h]	0.75	2	1.5	7-10	15
Rice	0.75	2	1.5	7-10	15
Rye [h]	0.75	2	1.5	7-10	15
Wheat	0.75	2	1.5	7-10	15
Cucurbit Vegetables					
Melons [i]	0.5	5	2.5	7	7

Table 5. Methyl Parathion Typical Use Patterns for EC Formulations *(continued)*.

Crop	Typical Single Application Rate (lbs a.i./A)	Typical Number of Applications per Year	Typical Amount Applied per Year (lbs a.i./A) [1]	Typical Application Interval (days)	Typical Pre-harvest Interval (days)
Fruiting Vegetables					
Peppers [i]	1.0	5	5.0	7	15
Miscellaneous Crops					
Artichokes (globe)	1.0	4	4.0	7	7
Cotton [j]	2.0	3	6.0	7	7
Hops [k]	1.0	3	3.0	7	28
Rapeseed (canola)	0.5	2	1.0	7	28
Sunflowers	1.0	2	2.0	3-5	30
Non-Grass Animal Feeds					
Alfalfa	0.5	1/cutting	2.5	7	15
Grass, Forage, Fodder, and Hay					
Grass	0.5	1/cutting	1.0	7	15

a. The maximum amount of methyl parathion allowed to be applied per season was calculated by multiplying the typical single application rate by the typical number of applications made per season.

b. No data have been submitted to support this use. According to the November 24, 1992, Methyl Parathion Residue Chemistry Registration Standard Update, data can be translated from broccoli to support this use. The use pattern specified in this table is based on the use pattern for broccoli.

c. The preharvest interval of 10 days applies if the final application is less than 1.0 lb a.i./acre. A 21-day minimum preharvest interval applies if the final application is 1.0 lb a.i./acre or more.

d. No data have been submitted to support this use. According to the November 24, 1992, Methyl Parathion Residue Chemistry Registration Standard Update, data can be translated from mustard greens to support this use. The use pattern specified in this table is based on the use pattern for mustard greens.

e. The preharvest interval of 10 days applies if the final application is less than 1.0 lb a.i./acre. A 15-day minimum preharvest interval applies if the final application is 1.0 lb a.i./acre or more. Typically, peas are harvested as much as 21 days after the last application.

f. Cheminova is supporting the use of the EC formulation of methyl parathion on this crop; however, it will not support the use on forage and hay. Cheminova plans to add a feeding/grazing restriction to its end-use labels to exclude use on forage and hay.

g. Cheminova will support a cereal grain crop group tolerance, but it will not support the use of the methyl parathion EC formulations on sorghum.

h. Cheminova is supporting the use of the EC formulation of methyl parathion on barley, oats, and rye. In the 90-day response to the April 10, 1997, data call-in notice for methyl parathion, Cheminova requested that EPA translate data submitted for wheat to support the use of the methyl parathion EC formulation on these crops.

i. This is a new use supported by IR-4. Cheminova does not intend to submit any data to support this use. The use patterns reported here is the use pattern proposed by IR-4.

j. The typical application rates for cotton are directly related to the target pest present during a particular growing season. In most years, methyl parathion will only be used against one or two of these pests.

Table 6. Methyl Parathion: Typical Use Patterns for the Mcap Formulation.

Crop	Typical Single Application Rate (lb a.i./A)	Typical Number of Applications Per Year	Typical Maximum Amount Applied Per Year	Typical Application Interval (days)	Typical Pre-Harvest Interval (days)
Root and Tuber Vegetables					
Potatoes	0.375	1	0.375	NA*	15
Sweet potatoes	0.375	1	0.375	NA	15
Bulb Vegetables					
Onions	0.375	1	0.375	NA	15
Legume Vegetables					
Beans, dry	0.25	6	1.5	5	15
Beans, succulent	0.25	2	0.5	7	3
Lentils	0.5	3	1.5	11	14
Peas	0.375	1	0.375	NA	15
Soybeans	0.25	1	0.25	NA	30
Pome Fruits					
Apples	0.625	2	1.25	7	21
Pears	0.625	1	0.625	NA	28
Stone Fruits					
Cherries	0.375	2	0.75	7	14
Nectarines	0.5	1	0.5	NA	28
Peaches	0.375	2	0.75	7	21
Plums/prunes	0.435	2	0.87	7	28
Fruiting Vegetables					
Tomatoes	0.25	1	0.25	NA	15
Tree Nuts					
Almonds	2.0	6	12.0	21	14
Pecans	0.435	2	0.87	21	51
Walnuts	0.875	1	0.875	NA	30
Cereal Grains					
Barley	0.375	1	0.375	NA	21
Corn	0.25	2	0.5	14	30
Oats	0.375	1	0.375	NA	21
Rice	0.375	1	0.375	NA	21

Rye	0.375	1	0.375	NA	21
Wheat	0.375	1	0.375	NA	21
Miscellaneous Crops					
Cotton	0.125	5	0.625	3	7
Grapes	2.5	3	7.5	7	60
Peanuts	1.0	4	4.0	14	15

*NA = not applicable because there is only one application.

Table 7. U.S. EPA Estimates of the Amount of Methyl Parathion Used in the United States from a Survey Conducted by the National Center for Food and Agricultural Policy for 1991-1993 and 1995.

Ranking	Crop	Total Amount Used Per Year (lbs a.i./crop/year)	Percent of the Total Amount Used on This Crop Each Year (%)
1	Cotton	3,396,754	57.0
2	Field corn	770,991	13.0
3	Alfalfa	418,692	7.0
3	Wheat	308,430	5.2
4	Sunflowers	217,221	3.7
5	Apples	177,141	3.0
7	Rice	149,555	2.5
8	Soybeans	115,659	2.0
9	Peaches	93,511	1.6
10	Potatoes	70,505	1.2
11	Sweet corn	59,912	1.0
Subtotal of Top 11 Uses		5,778,371	97.2
Subtotal for All Other Uses*		183,369	2.8
Grand Total		**5,961,740**	**100.0**

* Includes usage of methyl parathion on pecans, cherries, grapes, and sweet potatoes that were included in EFED's risk assessments.

IV. STUDY REQUIREMENTS

The EFED review states that most of the environmental fate and ecological data requirements for methyl parathion have been satisfied, but lists five specific data gaps for environmental fate and three for ecological effects, as well as one general comment on the adequacy of data on the formation of methyl paraoxon in the environment.

A. Laboratory Studies

1. Guideline #162-1: Aerobic Soil Metabolism (Upgradeable)

EPA's original review of this study concluded that the High Performance Liquid Chromatography (HPLC) method used was inadequate to separate methyl parathion from its metabolites. The reason for this conclusion was that para-nitrophenol (PNP) appeared in two different positions in the HPLC chromatograms: at its expected retention time and in the void volume. In response to this conclusion, Cheminova provided information that explained this phenomenon (MRID 43127604). The current draft EFED chapter states only that there are uncertainties associated with analytical procedures in metabolite quantification. Presumably, the EFED conclusion is based on the original conclusion in the 1992 Data Evaluation Record (DER). Cheminova believes that the information it provided in response to that DER satisfactorily explains the apparent finding of PNP in two places. However, given the short time available to prepare this 15-day response to the EFED RED and the uncertainty associated with the apparent finding by thin-layer-chromatography (TLC) of other radioactive residues in the HPLC chromatography peaks corresponding to the metabolites o,o-bis(4-nitrophenyl) - o- methyl phosphorothioate and PNP, Cheminova will submit more detailed comments on this study during the 60-day RED comment period.

The draft EFED chapter also includes the general comment that the formation of methyl paraoxon cannot be quantified with existing data. In this study, an authentic sample of methyl paraoxon was used to establish the chromatographic behavior of methyl paraoxon in the analytical methods used. The study results demonstrate that the mass balance accountability of all radioactivity in the test system was very good (average = 95.7%; range = 91.26% to 101.01%). Methyl paraoxon would have been detected in this study if it had formed, and in fact was detected in the parallel anaerobic aquatic metabolism study. At day 3 in the aerobic soil study, the amount of methyl parathion remaining in the test system began to decline rapidly, with a corresponding increase in the release of radioactive carbon dioxide. There is no indication of a peak in the radiochromatogram of soil extracts that corresponds to the known retention time of methyl paraoxon in the HPLC method used. The rapid formation of radiolabeled carbon dioxide is evidence that the dominant pathway of soil metabolism of methyl parathion is by destruction of the phenyl ring. This information demonstrates that methyl paraoxon is neither a detected nor an expected metabolite of methyl parathion in soil.

2. Guideline #162-3: Anaerobic Aquatic metabolism (Not Satisfied)

EFED concluded that the anaerobic aquatic metabolism study can be upgraded by submission of new storage stability data and additional information on the identification of degradates. Because of the complex issues of degradate identification and storage stability, as well as the short time available to prepare this 15-day response to the EFED RED, Cheminova will submit more detailed comments on this study during the 60-day RED comment period.

Also in this study, an authentic sample of methyl paraoxon was used to establish the chromatographic behavior of this potential degradate in the analytical methods that were used. The amount of radioactivity in actual study samples that exhibited the chromatographic behavior of methyl paraoxon never exceeded 2.1% of the dose of methyl parathion.

3. Guideline #163-1: Adsorption/Desorption (Rejected)

EPA rejected this study because the soils tested were autoclaved. Although this experimental procedure was acceptable at the time the study was completed and submitted, Cheminova will repeat this study when a formal DCI notice is issued with the RED. Degradate mobility will be examined in the repeat study.

B. FIELD STUDIES

1. Guideline #163-3: Field Volatility (New Requirement)

The EFED chapter notes that USGS detected methyl parathion in air samples in Alabama, Florida, and Mississippi, and that other air sampling data are also available. Cheminova believes that the aggregate array of air monitoring data are adequate to characterize air levels of methyl parathion. Cheminova also notes that the current use of methyl parathion is much less than was the case when the air monitoring studies were conducted, and that current concentrations will be correspondingly lower.

Cheminova is currently conducting a comprehensive risk assessment of air exposure associated with the use of methyl parathion; the preliminary results indicate that the methyl parathion levels in air are not a health concern. Cheminova plans to submit the results of this risk assessment to EPA during the 60-day comment period.

2. Guideline #164-1: Field Dissipation (Partially Satisfied)

The draft EFED chapter accepts one field dissipation study but rejects a parallel study because it concludes that the concentration in soil immediately following the final application was too low to establish a pattern of decline. These two studies were conducted in California and Missouri and had the same design, which was six applications of methyl parathion to cotton at weekly intervals at a rate of 1 lb a.i. per acre. In each study, residues of methyl parathion following each weekly application ranged from 0.087 ppm to 0.37 ppm in the top 4 inches of soil. In the California study the level of methyl parathion in soil one day after the last application was 0.033 ppm, whereas in the Missouri study no methyl parathion was detectable on the day after application at a limit of detection of 0.05 ppm. Methyl parathion was not detected at any other time point in either study, and methyl paraoxon was never detected in either study at the same limit of detection.

In the California study, the day zero application resulted in an immediate residue level of 0.37 ppm, while the sample taken immediately after the last of the six applications (day 35) contained 0.085 ppm. Thus, each of these sample results reflects the residue level found immediately after application. The day 36 sample represents the soil residue levels of methyl parathion one day after the last application; the average residue value found for this sample was 0.033 ppm. From the original study report, the individual replicate sample values were <0.05 ppm, 0.10 ppm, and <0.05 ppm. (The performing laboratory calculated an average value of 0.033 ppm by adopting the convention that soil concentrations below the limit of detection would be set to zero when at least one of the three replicates had a positive value.) Thus, in the case of the California study, a single positive detection of methyl parathion in a single replicate resulted in the reported average value of 0.033 ppm (a value that is actually below the limit of detection). In the Missouri study all three of the day 1 samples following the last application were below the 0.05 ppm detection limit. This is the only difference in the results between the two studies.

The reports for each study do not contain calculations for rates of dissipation for methyl parathion, although the original EPA DER concluded that the rate is about one day in the California study. This conclusion is clearly applicable to both studies. Cheminova believes that a single detection on day 1 after the last application in one replicate does not constitute a major difference between the two field studies. In fact, both studies demonstrate a rapid dissipation for methyl parathion in treated field soils. The lack of any buildup of soil residues following the six sequential applications is further evidence of a consistent and rapid dissipation of methyl parathion.

Cheminova understands that Elf Atochem will conduct field dissipation studies with Mcap to support the Mcap registration.

3. **General Comment on Environmental Formation of Methyl Paraoxon**

It is also important to make a general comment about available information on the quantification of methyl paraoxon. All of the laboratory studies conducted on methyl parathion used radiolabeled material in order to ensure complete accountability of all metabolites or degradates formed. All of these laboratory studies used authentic methyl paraoxon as a reference standard, in order to determine where methyl paraoxon would appear in the chromatographic procedures used. In six degradation and metabolism studies conducted and submitted, methyl paraoxon was found definitively only in the anaerobic aquatic metabolism study, although at less than 2.1% of the applied parent compound. Methyl paraoxon was also identified tentatively in the aqueous photolysis study at a very low level. Cheminova believes this array of Guideline studies provides sufficient information on the formation of methyl paraoxon in the laboratory studies as required by OPP's environmental fate test battery.

In the various terrestrial and aquatic field studies, the analytical methods used for water and soil are capable of detecting methyl paraoxon; however, none was detected in any of these studies.

Cheminova believes that the submitted studies adequately define the pathway of degradation, metabolism, and overall dissipation of methyl parathion, and that methyl paraoxon is at most only a minor environmental degradate or metabolite. The major pathway of degradation of methyl parathion is by hydrolysis to form PNP, followed by substantial mineralization of the phenyl ring to carbon dioxide.

C. ECOLOGICAL TOXICITY STUDIES

1. EFED contradicts itself concerning the estuarine/marine chronic toxicity study. In the October 27, 1998, cover memorandum, EFED indicates that an estuarine/marine invertebrate chronic toxicity study with methyl parathion is required; however, on page 37 of the draft RED chapter, EFED indicates that this data requirement is fulfilled (Lowe, 1981; MRID 00066341).

2. EFED contradicts itself concerning the necessity of conducting nontarget terrestrial plant studies. On page 38 of the EFED chapter, EFED indicates that these data are not needed, while on page 68 EFED indicates that these data are required. Cheminova is in the process of obtaining the references cited by EFED and will provide additional comments on this issue during the 60-day comment period.

3. Cheminova questions the utility and value of generating additional data on algae. Available data indicate low toxicity of methyl parathion to algae. EFED's additional rationale for requiring these data, a domino-like food chain theory, has been demonstrated to be flawed in a series of publications addressing food web

interactions (including publications from the U.S. Fish and Wildlife Service). Cheminova plans to elaborate on this point during the 60-day comment period.

V. ENVIRONMENTAL FATE ASSESSMENT

A. GENERAL COMMENTS

1. Before proceeding to a detailed critique of EFED's surface water assessment, it is important to draw attention to the inappropriate structure of the PRZM/EXAMS modeling system. In particular, PRZM assumes a 10 hectare field planted with only one crop draining into a pond with a 1 hectare area and 2 meters deep that is immediately adjacent to the field. These parameters are not an accurate reflection of a watershed large enough to support a drinking water facility. In addition, it is unrealistic to assume that the pond has no outlet.

   In its review, EFED at times concedes that there are serious problems with PRZM/EXAMS. In particular EFED notes that "no adequate validation has yet been made of PRZM3.1 for the amount of pesticide transported in runoff events." Pesticide transport in runoff is the essence of this model; thus, the lack of validation of this portion of the model raises serious concerns about the reasonableness of the model predictions.

2. Cheminova is concerned that EFED solicited input from agricultural experts concerning the use of methyl parathion on the nine crops selected for the PRZM/EXAMS modeling, and then did not use this information. Instead of constructing use scenarios that reflect the realities of methyl parathion use, EFED devised hypothetical, worst-case use scenarios, and then used the results from these scenarios to draw real-world conclusions. EFED's reliance on unrealistic use scenarios seriously undermines the confidence, reliability, quality, and validity of the conclusions EFED draws concerning risks posed by actual use of methyl parathion.

3. Cheminova requests that EFED provide the chemical-specific input parameters that EFED selected for PRZM/EXAMS and GENEEC modeling of both the EC and Mcap formulations of methyl parathion. Based on information currently available to Cheminova, it appears that EFED used the same chemical-specific properties to model these two very different formulations. If so, the aquatic modeling for one or both formulations is based on erroneous inputs. Cheminova also requests that EFED provide the inputs it used to estimate drift, surface runoff, and downward soil movement of the Mcap formulation, because this formulation is not expected to behave such that it can be modeled adequately using the standard default assumptions.

4. Cheminova has concerns with EFED's reliance on GENEEC modeling to draw meaningful conclusions about potential aquatic risks associated with uses of methyl parathion for a number of crops. Cheminova notes that EFED provides both PRZM/EXAMS modeling results and GENEEC modeling results for four crops (corn, alfalfa, peaches, and cotton). Comparisons of the PRZM/EXAMS results for these crops with the GENEEC results indicates that GENEEC predicted the aquatic concentrations to be 2-fold to 8-fold higher than PRZM/EXAMS, which is overly conservative itself. These considerations result in very low confidence in any conclusions EFED draws concerning the aquatic risk of methyl parathion for those crops modeled using GENEEC.

B. SELECTION OF ENVIRONMENTAL FATE PARAMETERS

Cheminova has reviewed in detail the major parameters selected by EFED for its PRZM/EXAMS modeling. In several instances, Cheminova's review and analysis identified more appropriate values that should be used to calculate more accurate EECs. Table 8 provides a list of the major chemical-specific values in PRZM and a list of the values chosen for these parameters by EFED and Cheminova. Table 9 provides a similar list for EXAMS. Explanations are provided below for those parameters wherein Cheminova believes that values different from those chosen by EFED are appropriate.

1. Soil Adsorption Constant (K_{oc})

Perhaps the most important chemical-specific parameter in PRZM, the soil adsorption constant (K_{oc}) determines the partitioning of the pesticide between the soil and aqueous phases. Higher values mean more pesticide in the adsorbed phase as opposed to the soluble phase of the runoff. This results in lower EECs. EFED chose a value of 487 (dimensionless) for this parameter in PRZM and EXAMS. This value is based on a batch equilibrium experiment conducted by Cheminova using radiolabeled methyl parathion in autoclaved (i.e., sterilized) soils (MRID 40999001). While autoclaving soils was appropriate using the EPA guidance at the time the study was conducted (1988), it alters the surface of the soil resulting in a lower affinity for organic matter. EFED subsequently revised its guidance on conducting this study, and rejected the batch equilibrium study submitted by Cheminova. Cheminova plans to conduct a new study.

EPA's Office of Research & Development (ORD) critically reviewed data on pesticide adsorption/desorption in soil (Rao and Davidson, 1982) and created a database of such values for use in non-point source modeling of pesticides. ORD reports a range of methyl parathion K_{oc} values from 346 (in a soil with very high organic matter content) to 15,930 (in a soil with very low organic matter content). These values can be compared to K_{oc}s for ethyl parathion, the ethyl analog of methyl parathion, which are in the range of 3,400 to 21,000. Based on the relative water solubility of these two compounds, 60 ppm for methyl parathion, and 24 for ethyl parathion, soil adsorption is expected to be greater with ethyl parathion (higher K_{oc}), but within the same range. Additionally, the United States Department of Agriculture (USDA) Pesticide Properties Database lists a K_{oc} of 5,100 for methyl parathion and 5,000 for ethyl parathion, and the Pesticide Information Retrieval System (Environment Canada, 1992) recommends these same values. It therefore seems appropriate to use a value of 5,100 for the K_{oc} of methyl parathion for purposes of soil runoff and aquatic modeling. As noted above, Cheminova will conduct a new study according to current guidance.

2. Aerobic Soil Metabolism

EFED's selection of an 11.25 day half-life for this model input parameter was based ostensibly on a laboratory study of ring-labeled methyl parathion in sandy loam soil that was incubated in the dark at 25°C (MRID 41735901). EFED determined that the degradation was biphasic and calculated a half-life in this study of 3.75 days using nonlinear curve fitting techniques. Employing the EFED policy of multiplying by a safety factor of 3 if there is only one degradation study available results in a half-life of 11.25 days. Cheminova strongly disagrees with this policy because, in this case, it results in a half-life that is so unrealistic it essentially suggests that reapplication of the pesticide at the suggested intervals is unnecessary.

In addition, EFED apparently did not apply this value consistently throughout each of the scenarios. Table 10 of this document presents the values used by EFED for the dissolved phase and adsorbed phase aerobic degradation rate constants for each of the scenarios. These values correspond to a range of half-lives of 4 to 301 days. It is not clear why a half-life of 11.25 was not used for all of these values. Also, it is not clear why, in some cases, different values were chosen for the dissolved and adsorbed phases. Normally, the contribution from these phases cannot be separated in a degradation study. This mistake should be corrected in later model runs.

Cheminova believes that EFED should rely on the two terrestrial field dissipation studies to estimate the aerobic soil half-life. The first study, conducted in California, included applications of methyl parathion to cotton on sandy loam soil (MRIDs 41481001 and 41752501). As EFED states, "Methyl parathion rapidly dissipated with a half-life of approximately 1 day." Cheminova agrees with this assessment.

The second study, which was conducted in Missouri, included applications of methyl parathion to cotton in loam soil (MRID 41481002 and 41752502), and was deemed unacceptable by EFED because "the concentration of methyl parathion in the soil immediately following the final application was too low to establish a pattern of decline." (See Cheminova's discussion of the acceptability of this study in Section IV.) EFED recommends that an additional study be required to supplement the California study. However, there are sufficient measurements in the Missouri study, which included applications of methyl parathion to cotton in loam soil, to ascertain an upper bound on the half-life that is consistent with the California study.

Table 11 provides a summary of the methyl parathion concentrations measured in the Missouri study. It is important to note that this study included six weekly applications of methyl parathion at 1 lb a.i./acre. The methyl parathion measurements during the first six weeks were made immediately after each application. Subsequent measurements were made one day after the final application and at one week increments thereafter. Regarding these data, EFED states "The Missouri study showed no such evidence of decline [relative to the California study]. The average residue concentrations on days 0 and 7 are 0.039 and 0.030 ppm, respectively." However, the measurement at day 7 was following an additional application; thus, if there were complete degradation of the methyl parathion applied at day zero during the 7 day period, roughly similar concentrations would be expected for both measurements, which is what was observed. Cheminova agrees that it may be difficult to construct a detailed dissipation curve from these data. However, there is clearly no build-up of methyl parathion during the first six weeks. Build-up should occur if the half-life is not significantly less than one week. For example, if the half-life were 11.25 days, as EFED assumes, then significant build-up should be evident. On the other hand, if the half-life were 1 day as was found in the California study, the methyl parathion would be reduced to approximately 1% of its original concentration after seven days. This half-life would more reasonably explain the data in the Missouri study, and it is consistent with the California study. Therefore, Cheminova believes that a soil half-life of 1 day should be used for the runoff modeling.

3. Foliar Dissipation

EFED neglects to consider foliar dissipation for methyl parathion in its PRZM simulation, essentially assuming that dissipation does not occur. In fact, there is considerable evidence that methyl parathion quickly dissipates from leaf surfaces. For example, Fritz (1992) measured the foliar dissipation of methyl parathion from apple seedlings and found a dissipation half-life of approximately 5 hours.

Numerous researchers have also examined the dissipation of methyl parathion on cotton. Ware et al. (1975) determined that methyl parathion dissipation on cotton ranged from 4.8 hours to 38 hours. Willis et al. (1985) reported that the disappearance half-life of methyl parathion was 2.4 hours for cotton. Additionally, Smith et al. (1987) reported half-lives of 4.4 hours and 5.4 hours from cotton surfaces following EC applications.

Cheminova urges EFED to consider these other studies and determine an appropriate foliar half-life of methyl parathion instead of assuming that foliar dissipation is nonexistent. Cheminova's analysis of these data suggests an upper-bound value of 1 day is appropriate for the foliar dissipation half-life.

It is also worth noting that EFED has modeled methyl parathion applications on cotton that are, in some cases, 3 days apart. If the aerobic soil half-life were actually 11.25 days (see previous discussion) and there is no foliar dissipation, it would not be as imperative to reapply the pesticide as frequently as is assumed in the PRZM model. Therefore, EFED needs to consider a lower aerobic soil half-life and an appropriate foliar half-life to be consistent with use pattern assumptions in the model.

4. Bacterial Degradation in Water

In EXAMS, EFED assumed a value of 6.25 days for the bacterial degradation of methyl parathion in water. Cheminova is not clear how EFED derived this value. Cheminova believes that an appropriate value for this parameter can be obtained from the aerobic (Patterson, 1991, MRID 42069601) and anaerobic aquatic metabolism (Patterson, 1990, MRID 41768901) studies which were conducted according to EPA guidelines.

The anaerobic study measured the degradation of radiolabeled methyl parathion in the dark using a sandy soil. The soil had a viable microbial population both before and after the study. The soil/water system was incubated anaerobically for 23 days, and then glucose was added before an additional 47 days of anaerobic incubation. This was followed by dosing with methyl parathion. The half-life was approximately 1.1 days, which is the value Cheminova recommends for the EXAMS model. No methyl parathion was detectable in the soil/water system after 7 days.

The aerobic aquatic metabolism study was conducted with a microbially active sandy loam soil that was flooded with well water. In this system methyl parathion degraded with a half-life of 1.1 days during the first 7 days of the study. Because methyl parathion was nearly totally degraded by 7 days (slightly more than 6 half-lives), this value seems to be the most appropriate half-life to utilize for aquatic modeling.

Because both the aerobic and anaerobic aquatic metabolism studies indicate a very rapid dissipation of methyl parathion in aquatic environments, Cheminova believes that the 1.1 day half-life is a reliable value to use in the aquatic fate modeling of this chemical.

5. Application During Heavy Rainfall

In the PRZM model, the applications of methyl parathion were assumed to occur on the same day in each year of the 36-year simulation. This has resulted, perhaps unintentionally, in applications during extreme rainfall events, which leads to abnormally high runoff levels. The effectiveness of the pesticide is diminished after it is washed off the plant or drained from the soil; therefore, farmers are normally cognizant of rainfall forecasts and would likely not apply a pesticide on days with heavy rainfall. It is possible that a farmer would apply a pesticide on a particular morning followed by a non-forecast rainfall event. However, Cheminova believes that there should be some reasonable level of rainfall where it is expected that the event will be forecast or it will rain the entire day, thus preventing an application before the rain started. A reasonable value for this cut-off is 3 cm of rainfall in a day.

Cheminova has reviewed the meteorological data files used in the PRZM simulations and found that there was more than 3 cm of rainfall on a number of application days. In these cases, the application should be switched to the following day, assuming there was not high rainfall on that day also.

6. Summary

This section provides five examples of problems that Cheminova has found with the environmental fate assumptions EFED uses in their surface water assessment. Cheminova urges EFED to carefully review these comments and make appropriate revisions. During the 60-day public comment period, Cheminova intends to implement these revisions (and others likely) to produce revised EECs for surface water.

C. Water Monitoring Assessment

Actual measurements are always preferable to theoretical model estimations when comparing health effects to environmental concentrations. Therefore, Cheminova has dedicated a considerable effort to reviewing available water monitoring data.

1. Groundwater

For groundwater, EFED uses the SCI-GROW screening model, and states that without groundwater monitoring data no refinement of this assessment can be made. Accordingly, EFED proposes to require a groundwater monitoring study. However, the Agency's groundwater assessment ignores both USGS groundwater monitoring data and the available data from EPA's own Pesticides in Groundwater Database (PGWD; September 1992). The USGS NAWQA Program monitors pesticides in groundwater. During the period of 1992 to 1995, USGS NAWQA reported no detections of methyl parathion in groundwater, though several thousand samples were analyzed for methyl parathion (for the vast majority of the samples the method limit of detection of 0.006 ppb). EPA mistakenly suggests on page 25 of the EFED chapter that the maximum measured concentration in NAWQA for groundwater was 0.062 ppb. In fact, this concentration was a detection limit for a few of the samples. The PGWD summarizes monitoring data from 1971 to 1991, including both methyl parathion and methyl paraoxon. Methyl paraoxon was only analyzed for in 125 samples from Mississippi and California (two important states with large usage) and was never detected. Methyl parathion was only detected in 20 samples from 3,357 discrete wells sampled for methyl parathion from 1982 to 1991. Concentrations ranged from 0.01 ppb to 0.256 ppb.

Cheminova is in the process of obtaining these studies and will provide comments on them during the 60-day comment period.

The extensive monitoring for methyl parathion in groundwater from USGS NAWQA study sites across the United States for four years, as well as the large body of historical monitoring data in the PGWD, indicate that any potential exposure to methyl parathion in drinking water derived from groundwater is extremely small. The known rapid dissipation of methyl parathion after application to terrestrial or aquatic crops precludes its survival for periods of time that are sufficient to allow subsurface transport to aquifers used as sources of drinking water. These data demonstrate conclusively that a groundwater monitoring study on methyl parathion is not needed.

2. Surface Water

Methyl parathion in surface waters has also been monitored extensively in the USGS NAWQA Program. This program analyzed 5,218 surface water samples from the period of January 16, 1992, to December 16, 1996; methyl parathion was rarely detected. The USGS methods for detection of methyl parathion have a method detection limit of 0.006 ppb. Only 36 detections of methyl parathion, in the range of 0.3 to 0.006 ppb, were found in the 5,218 samples (0.69%). Several of the NAWQA study units include areas where methyl parathion use is substantial, particularly the Mississippi Embayment and the San Joaquin-Tulare Basins. These USGS NAWQA data represent a much larger database than the Agency reviewed in the draft RED. Cheminova agrees with EPA that the monitoring data are reliable. However, Cheminova also notes that the rare, low level detections in these studies are **not** in drinking water, but are from rivers, lakes, and even small streams in agricultural areas. These sources are likely too small to serve as sources of drinking water; in addition, water samples from these sources have not been processed through community water system treatment plants.

Another very useful targeted surface water monitoring database is that developed by the California Department of Pesticide Regulation (CDPR) for pesticides, including methyl parathion, that are used on rice in California. This study has been in progress for 10 years and samples are taken every 2 to 5 days during the rice use season of mid-April to mid-June. These data can be considered as representative of relatively worst-case runoff events because runoff is excessive from flooded rice fields, soils are heavy clays, and the relatively high frequency of sampling should capture peak concentrations in runoff. However, these results also demonstrate the effectiveness of spray drift mitigation procedures which have been implemented in California during the course of this rice study. Keeping these factors in mind, methyl parathion in surface water was detected infrequently in the range of 0.05 to 0.19 ppb, while the vast majority of results are <0.05 ppb (the method reporting limit). While these study results are very useful because they represent relatively worst-case runoff events, they cannot be considered typical of other agricultural use patterns of methyl parathion.

In Figure 1 the results from the NAWQA data are compared to the GENEEC cotton scenario estimate and the peak (instantaneous) values derived from the nine crop-specific PRZM/EXAMS scenarios modeled by the Agency. Obviously the 90^{th} percentile EECs predicted by GENEEC and the more refined PRZM/EXAMS modeling are gross overestimations of the actual surface water concentrations of methyl parathion. The problems with the PRZM model are discussed above. More importantly, the Agency must realize the greater reliability of the surface water monitoring data as compared to the modeling results.

The extensive monitoring for methyl parathion in surface waters indicates that any potential exposure to methyl parathion in drinking water derived from surface water is extremely small. These data are also in dramatic contrast to the EECs calculated by EFED using PRZM/EXAMS.

Figure 1

Table 8. Comparison of the Chemical and Environmental Fate Inputs Selected by EFED and Cheminova for Conducting the PRZM Runoff Modeling for Methyl Parathion

Parameter	Values Selected by EFED	Values Selected by Cheminova
Molecular Weight	265 g/mole	265 g/mole
Water Solubility	60 ppm	60 ppm
Soil Adsorption Constant (K_{oc})	487	5100
Vapor Pressure	9.7×10^{-6} mm Hg	9.7×10^{-6} mm Hg
Aerobic Soil Half-Life (in both dissolved and adsorbed phases)	4 days to 301 days	1.0 days
Pesticide Volatilization Decay Rate on Foliage (days^{-1})	0.0 (stable, half-life = 1,000 days)	0.0 (stable, half-life = 1,000 days)
Pesticide Decay Rate on Plant Foliage (days^{-1})	0.0 days $^{-1}$ (stable, half-life = 1,000 days)	0.693 days $^{-1}$ (half-life = 1.0 days)
Foliar Extraction Coefficient for Pesticide (proportion washed off/cm of precipitation)	0.5	0.5

a.

Table 9. Comparison of the Chemical and Environmental Fate Inputs Selected by EFED and Cheminova for Conducting the EXAMS Aquatic Fate Modeling for Methyl Parathion.

Parameter	Values Selected by EFED	Values Selected by Cheminova
Molecular Weight	265 g/mole	265 g/mole
Water Solubility	60 ppm	60 ppm
Soil Adsorption Constant (K_{oc})	487	5100
Vapor Pressure	9.7×10^{-6} mm Hg	9.7×10^{-6} mm Hg
Log K_{ow}	2.97	2.97
Henry's Law Constant	6.12×10^{-7}	6.12×10^{-7} m^3/mol
Aqueous Hydrolysis Half-life	40 days (at pH 7.0)	40 days (at pH 7.0)
Aqueous Photolysis Half-life	49 days	49 days
Aqueous Volatility Half-life	750 days	750 days
Bacterial Degradation in:		
Water Half-life	6.25 days	1.1 days
Sediment Half-life	0.79 days	0.79 days

Table 10. Summary of PRZM Soil Degradation Rates Used by EFED

Scenario	Dissolved Phase Rate Constant (days^{-1})	Adsorbed Phase Rate Constant (days^{-1})
Cotton	0.173	0.062
Corn	0.062	0.062
Alfalfa	0.062	0.062
Peaches	0.062	0.062
Potatoes	0.062	0.062
Pecans	0.062	0.0023
Cherries	0.062	0.062
Grapes	0.077	0.077
Sweet Potatoes	0.062	0.062

Table 11. Summary of Methyl Parathion Measurements in Missouri Field Dissipation Study

Sample	Days After the Initial Application	Methyl Parathion (ppb)
Prior to Application	-1	<0.05
Application 1	0	0.039
Application 2	7	0.030
Application 3	14	0.059
Application 4	21	0.087
Application 5	28	0.022
Application 6	35	0.052
1 DAT[a]	36	<0.05
7 DAT	42	<0.05
14 DAT	49	<0.05
21 DAT	56	<0.05
28 DAT	63	<0.05

[a] DAT = days after treatment. In this case, it refers to the number of days after the final application.

VI. ECOLOGICAL RISK

Cheminova provides the following preliminary comments on the ecological risk assessment. This section is divided into the following parts: (1) general comments on the ecological risk assessment, (2) comments on the aquatic risk assessment, (3) comments on the avian and mammalian risk assessment, and (4) comments on EFED's statements about bees. More extensive comments will be provided during the 60-day public comment period.

A. GENERAL COMMENTS ON ECOLOGICAL RISK ASSESSMENT

1. EFED has erroneously conducted risk assessments for the EC and Mcap formulations using the same toxicity values and exposure input parameters. These are two very distinct formulations, that have different toxicity values, environmental degradation and dissipation rates, and drift and runoff potential. Therefore, separate risk assessments should be conducted for each formulation.

2. Cheminova is concerned that there is a significant amount of unsubstantiated speculation in this draft RED chapter. Key examples include EFED's claims concerning indirect effects on organisms (such as food chain impacts, population-level impacts) and EFED's hypotheses about tank mixing of different pesticide products and/or sequential applications of different products to a crop. Any interactions among pesticide products, pesticides and other products, or food chain interactions. These assumptions are highly complex and are not easily predictable. The straightforward "domino-types" of effects and additive effects that EFED predicts are not supported by available studies and literature that have explored these hypotheses.

3. EFED's use of the Breeding Bird Survey to support claims that methyl parathion is responsible for declines of some of the species listed (page 73 of the EFED chapter) represents a misuse of the Breeding Bird Survey data. Numerous factors affect the bird population trends as tracked by the Breeding Bird Survey; many of the major factors affecting survey results are completely unrelated to any pesticide use, much less use of a specific pesticide. In this section of the draft RED chapter, EFED also misrepresents and exaggerates the use of methyl parathion on corn. EFED's risk quotient (RQ) procedure is focused on effects at the individual level of biological organization, not the population level; EFED's claims of population level impacts are unsupported by the available data, and because EFED has not performed a rigorous population level analysis, it should refrain from such speculations.

4. EFED should clearly acknowledge that its risk assessments represent screening level assessments rather than definitive assessments. As such, Level of Concern (LOC) exceedances should only be interpreted as meaning that more in-depth assessments need to be undertaken.

B. Comments on the Aquatic Risk Assessment

1. EFED indicates that it has a high degree of certainty concerning its conclusions about potential impacts of methyl parathion on estuarine/marine fish and invertebrates. However, in addition to the problems previously mentioned concerning EFED's modeling work (inappropriate choices for key model input parameters, unrealistic use scenarios), the receiving water body (a stagnant farm pond) is not representative of estuarine/marine water bodies, particularly those estuarine waters containing economically important species. The shortcomings of EFED's modeling procedures and resultant EECs lead to low confidence and high uncertainty being associated with any RQs calculated for estuarine/marine organisms.

2. Confidence in the aquatic EECs that EFED relies on as exposure inputs to its RQ calculations is severely undermined by the available surface water monitoring data (see Section V of this document). The monitoring data indicate that EECs associated with methyl parathion use are two or three orders of magnitude below the EECs generated by EFED's hypothetical modeling scenarios. This discrepancy most likely reflects some of the modeling shortcomings noted above (i.e., improper input parameters, unrealistic use scenarios, limitations resulting from the geographical relationship of the pond to fields, hydrology limitations of the pond).

3. EFED's overall characterization and conclusions concerning risk to aquatic invertebrates are based on significant shortcomings in its analysis that result in high uncertainty in the calculated RQs. As described above, substantial errors in the EEC modeling result in orders-of-magnitude overestimates of the EECs. These inflated EECs are then compared to a single aquatic toxicity value that EFED improperly portrays as being representative of the aquatic toxicity of methyl parathion to all aquatic invertebrates. However, daphnids alone cannot be considered as being representative of the wide variety of aquatic invertebrates. Even among those species in which methyl parathion has been tested, the testing resulted in LC_{50} or EC_{50} values one to two orders of magnitude higher than the value selected by EFED for its risk characterization, with the exception of one other daphnid value. Additionally, most of the other aquatic invertebrate testing with methyl parathion has focused on highly sensitive groups of organisms such as crustaceans and aquatic insects; tests on aquatic invertebrates belonging to other phylogenetic groups have resulted in toxicity values three to four orders of magnitude greater than (i.e., less toxic) the value EFED selected to characterize risk to all aquatic invertebrates. Thus, there is not only a high degree of uncertainty

associated with EFED's EECs, but also a corresponding uncertainty associated with the toxicity side of the risk equation that EFED has failed to acknowledge. The uncertainties on both the exposure and toxicity sides of the risk equation result in high uncertainty concerning EFED's risk conclusions about both freshwater and estuarine/marine invertebrates.

4. In Appendix 5 of the EFED chapter, which contains a listing of alleged aquatic and avian incidents involving methyl parathion, EFED appears to assign any potential incident to methyl parathion without a rigorous evaluation of the information provided. Therefore, EFED has included incidents in this Appendix, which based on even the limited amount of information provided by EFED, are clearly not attributable to methyl parathion. For example, numerous incidents that EFED attributes to methyl parathion are actually listed as being due to other factors, including algal blooms, low dissolved oxygen, or other pesticides. Due to these shortcomings, Cheminova believes that this section should be deleted.

C. COMMENTS ON AVIAN AND MAMMALIAN RISK ASSESSMENT

1. EFED fails to enunciate the basic underlying assumptions and limitations of its avian and mammalian exposure and risk assessments. Key assumptions that impact interpretation of EFED's analyses include the following: (1) birds and mammals feed only on pesticide-treated feed items throughout the exposure period; (2) all the pesticide-treated feed items that birds and mammals consume throughout the exposure period contain the maximum initial (day 0) estimated residues; (3) birds and mammals consume feed items from only one of EFED's feed item categories (e.g., short grass, insects, broadleaf foliage/forage, or seeds) throughout the exposure period; (4) no degradation or dissipation of the maximum initial estimated residues occurs during the exposure period; and (5) all the acreage planted for a specific crop is treated with the pesticide product.

2. EFED's multiple application exposure scenarios and resulting RQ calculations for birds and mammals are flawed. EFED concedes that methyl parathion dissipates rapidly in the environment, and cites data that indicate the foliar half-life for methyl parathion ranges from less than 1 day to approximately 13 days. EFED further indicates that it selected a foliar half-life of 2.4 days as the upper 90^{th} percentile value. However, EFED does not use these data when developing its multiple application scenarios, and instead calculates exposure and resultant risk (RQs) using strictly additive procedures, with no degradation/dissipation occurring between applications. For example, all the multiple application acute and reproduction RQ values listed in the table on pages 41 and 42 are simply the single application RQ values multiplied by the number of applications EFED uses in its exposure scenarios. This method results in significant overestimates of EECs on feed items and highly inflated RQs for multiple application scenarios.

3. Similarly, EFED's chronic, or longer-term, exposure scenarios and resultant RQ calculations for birds and mammals are flawed (see Tables on pages 41, 42, 51, and 52 of the EFED chapter). Although EFED concedes that methyl parathion degrades rapidly in the environment, and calculates an upper 90th percentile half-life value of 2.4 days, these data are ignored in EFED's calculations of longer-term reproduction and feeding RQs for both birds and mammals. Instead, EFED improperly compares longer-term toxicity endpoints (NOECs) derived from studies using continuous 90- to 150-day dietary exposures to initial maximum estimated residues on feed items. This represents a significant mismatch of toxicity and exposure data, resulting in a skewed mischaracterization of longer-term risk.

4. EFED's overestimation of methyl parathion exposure concentrations greatly outweighs EFED's claims that avian and mammalian exposure and risk may be underestimated because methyl paraoxon exposure values are not explicitly included in the estimates. EFED's text concerning exposure to methyl paraoxon in addition to parent methyl parathion is misleading because this text suggests that exposure to methyl paraoxon should be added to the initial estimated values for methyl parathion. Contrary to EFED’s speculations, methyl paraoxon is not the major metabolite of methyl parathion on avian and mammalian feed items. Residue data indicate that methyl paraoxon is nondetectable on many types of feed items, such as nuts, seeds, and fruits, and is found only in low concentrations on other types of feed items. The conversion of methyl parathion to methyl paraoxon is not 100%, as implied by EFED's text. Another key point is that methyl paraoxon, like the parent, is environmentally short-lived, and therefore any methyl paraoxon formation is also accompanied by degradation. Yet another key point that missing in EFED's text is that exposure to parent methyl parathion decreases when methyl paraoxon or other, less toxic degradates are formed.

5. EFED's discussion of the sublethal effects of methyl parathion on birds is misleading because EFED presents these as effects that only occur following exposure to methyl parathion. In fact, these types of sublethal effects occur following exposure to nearly all pesticide and non-pesticide products at concentrations below those that are lethal; thus, there is nothing unique about these effects being noted for methyl parathion.

6. In the avian and mammalian risk assessments and EEC calculations, EFED appears to be neglecting that there is at least 50% deposition efficiency associated with airblast and aerial applications to orchard crops and foliage because EFED's estimated residues on avian and mammalian feed items beneath the orchard canopy (e.g., grasses, broadleaf weeds, seeds, soil-dwelling insects and other invertebrates) are based on estimates for downward-directed applications to row crops. By ignoring the 50% or greater deposition on trees during applications to orchards, EFED is overestimating the concentrations on these key feed items by at least two-fold for these crop scenarios. This inaccurate overestimate has significant

implications for potential risk using EFED's RQ approach to characterizing potential risk.

7. EFED does not actually provide its estimated mammalian LC_{50} values in the draft RED chapter, and its method of arriving at the estimated LC_{50} values and resultant RQs is not presented clearly. However, based on the information provided, Cheminova has deduced that EFED is using estimated mammalian LC_{50} values of 3.78 ppm, 5.45 ppm, and 24 ppm for herbivores and insectivores with body weights of 15 g, 35 g, and 1000 g, respectively. Apparently, EFED has estimated daily feed consumption as a percentage of body weight as 95% for the 15-g animal, 66% for the 35-g animal, and 15% for the 1000-g animal. Similarly, EFED's estimated LC_{50} values for gramnivores that consume 21%, 15%, and 3% of their body weights (apparently relating to body weights of 15 g, 35 g, and 1000 g, respectively) are 17.1 ppm, 24 ppm, and 120 ppm, respectively. Cheminova requests that EFED provide references supporting its estimated daily feed consumption values as a percentage of body weight, particularly because EFED's estimates of daily feed consumption are much higher than values typically found in the published literature, including values referenced in EFED's *1986 Ecological Risk Assessment Standard Evaluation Procedure* and EPA's *1993 Wildlife Exposure Factors Handbook.*

8. Cheminova believes that EFED's estimated mammalian LC_{50} values greatly overestimate the dietary toxicity of methyl parathion to small mammals, and therefore greatly overestimate risk to these organisms. EFED's attempts to estimate LC_{50} values for mammals based on LD_{50} data introduce an inherently large amount of uncertainty into the risk evaluation that is not acknowledged by EFED. Often, such estimated LC_{50}s are substantially lower than actual LC_{50}s determined in testing (Hall and Fischer, 1997). EFED should acknowledge the large amount of uncertainty associated with its estimated LC_{50} values. Additionally, actual data on the dietary ingestion of methyl parathion by small mammals support the position that EFED's estimated LC_{50} values greatly overestimate the short-term dietary toxicity of methyl parathion to small mammals. Cheminova notes that many of EFED's estimated mammalian LC_{50} values are approximately equivalent to, or even lower than, no-observed effect concentrations determined in longer-term (90-day to 150-day) continuous dietary dosing studies conducted with methyl parathion. Cheminova also notes that acute or subacute (short-term) feeding studies have actually been conducted on small mammals with methyl parathion. Given the availability of these data, Cheminova sees no reason for EFED to introduce additional uncertainty to its risk analysis procedure by estimating the dietary LC_{50}; the available short-term LC_{50} values are 110 and 249 ppm for rats (MRID 43961101).

9. EFED's methodology for calculating longer-term (chronic) residues on avian and mammalian feed items for risk assessment is flawed. EFED is using single-day

maximum EECs as input values to its chronic risk assessment instead of a mean estimated concentration over the course of the exposure scenarios. This represents a serious mismatch of toxicity and exposure data; basically, EFED is comparing a single-day acute exposure estimate to longer-term (90-day to 150-day) toxicity end points. This approach is analogous to using an instantaneous EEC in aquatic modeling to estimate chronic exposure of aquatic organisms. For aquatic longer-term exposure, EFED more appropriately uses 21-day, 60-day, or 90-day average concentrations. The same principle applies to evaluating longer-term avian and mammalian risk, particularly for nonpersistent chemicals such as methyl parathion.

10. Cheminova believes that EFED has significantly overstated potential longer-term terrestrial organism exposure by using maximum estimated residue values rather than mean or typical estimated residues to characterize potential longer-term exposure to a pesticide product. Considering the assumptions underlying EFED's longer-term exposure scenarios, there is a vanishingly low probability that a bird or small mammal will continuously ingest feed items containing only maximum estimated residues over the duration of a longer-term exposure scenario. Cheminova intends to provide revised avian and mammalian longer-term risk evaluations using more appropriate longer-term exposure estimates. For example, preliminary results for a multiple application scenario to corn result in longer-term avian risk quotients of approximately 0.2 to 7 for various types of feed items; similarly, preliminary longer-term RQs for small mammals range from approximately 0.3 to 8. These preliminary RQs are 30 to 70 fold lower than EFED’s longer-term avian RQs. Although EFED did not calculate RQs for multiple applications to estimate mammalian RQs, Cheminova calculated multiple application RQs that are 10 to 15 fold lower than EFED’s single application RQs.

11. Cheminova has concerns with EFED's portrayal of acute EECs and risk to birds and mammals because the acute (short-term) exposures are incorrectly presented as definitive, "most likely" acute exposure scenarios when these scenarios actually represent extreme, "high-end" potential acute exposures. Cheminova intends to present more complete avian and mammalian risk assessments, covering both "most likely" and "high-end" exposure scenarios. Presenting potential exposure in this format provides one index of uncertainty associated with the risk assessment. For example, preliminary acute RQs for birds in a multiple application scenario on corn range from approximately 0.1 to 3.5 (15 to 32 fold lower than EFED’s RQs) for different types of feed items; similar preliminary mammalian RQs range from approximately 0.03 to 0.9 (30 to 55 fold lower than EFED’s RQs). These RQs differ significantly from the values presented by EFED.

12. Cheminova disagrees with EFED's estimated residues on large and small insects. Cheminova believes that EFED has erroneously applied the data in Fletcher et al. (1994) to insect feed items. Fletcher et al. (1994) does not discuss residues on insects. However, EFED has inappropriately lumped the two groups of insects in

with the revised values for broadleaf plants/forage and seeds/fruit based on a comment in the original Hoerger and Kenaga (1972) paper indicating that available data at that time suggested that residues on small insects were fairly close to the original estimated residues on forage (58 ppm) and that residues on larger insects were reasonably close to the original estimated values for seeds (12 ppm). In fact, data collated by industry from avian field studies (Brewer et al., 1997; Fischer et al., 1997) indicate that residues on insects are substantially (up to 2 orders of magnitude) less than EFED's estimated residues on insect feed items. This incorrect estimate of residues in/on insect feed items has significant impacts on EFED's avian and mammalian risk assessments.

13. Cheminova disagrees with EFED's postulation that the bioconcentration of methyl parathion in carnivorous/piscivorous feed items such as fish or tadpoles represents a significant exposure pathway of birds, mammals, or other fish because methyl parathion has a low bioconcentration potential and is rapidly metabolized and excreted by fish. Additionally, even EFED's greatly inflated aquatic EECs do not approach values in the 1 to 5 mg/L range which were needed in the study cited by EFED (e.g., Hall and Kolbe, 1980) to concentrate ethyl parathion and fenthion to lethal levels in tadpoles that were then force-fed to mallards.

14. Cheminova sees little relevance for the cold stress factor cited by EFED as an additional element that could increase the avian risk assessment of methyl parathion because methyl parathion applications to crops are not made under cold stress conditions (e.g., methyl parathion is not applied to crops at -5°C). Rather, methyl parathion is applied primarily in warmer climatic conditions, when target insect activity is high.

D. COMMENTS ON EFED'S STATEMENTS ON BEES

1. The table on pages 54 and 55 of the EFED chapter concerning bee incidents is missing some key information that is necessary to fully evaluate EFED's claims concerning bee incidents. Most significantly, this table fails to provide any information concerning the number of beekeepers that the survey was sent to, or even data about the number of beekeepers in each of the states listed. This type of information is crucial to evaluating the results of these types of surveys (e.g., do the incidents listed represent 0.1%, 1%, 10%, etc. of the hives in these states). Furthermore, it is not clear how EFED's table includes 100 to 300 colonies reported as damaged in states in which no beekeepers responded, and that are listed as having zero colonies in operation according to the survey.

2. EFED lists a number of bee incidents allegedly being attributed to methyl parathion in Appendix 2 of the EFED chapter. However, for many of these incidents, no effects are reported, which raises significant questions about the usefulness of the information provided. Additionally, for many of the incidents that EFED is

attributing to methyl parathion, other pesticides, such as guthion, chlorpyrifos, phosmet, and endosulfan, which are also toxic to bees, were used and/or detected. Therefore, it appears that EFED is simply attributing incidents to methyl parathion regardless of whether methyl parathion was even present or used in the vicinity.

3. The American Beekeeping Federation Survey does not provide a statistically relevant portrayal of the situation. The opinions of the beekeepers are based on data which cannot be used to measure the impact of environmental factors (such as mites, weather, pesticides) on colony damage. The results of this survey therefore cannot be relied upon for providing statistically relevant data for EFED's purposes.

4. On page 78, the statement on the EECs calculated for bees and <u>beneficial</u> insects is inaccurate. How does EFED define the level of concern? On page 39, EFED indicates it does not currently perform risk assessments for nontarget insects. In contrast, on page 78 EFED's claims for EECs for bees infers that EFED has performed some sort of quantitative assessment for nontarget insects. However, EFED has not explicitly presented its EECs for nontarget insects. In the 1998-1999 *Pennsylvania Tree Fruit Production Guide,* published by Pennsylvania State University, the chart from page 169 clearly demonstrates that Mcap is only slightly toxic to beneficial insects in comparison to the majority of the alternatives.

5. The experience of Elf Atochem contradicts EFED's statement that current label language and mitigation measures have not sufficiently reduced the risk of methyl parathion use to honeybees. Since 1992, there have been very few complaints about bees being killed by Mcap. This can be attributed to the label language changes, educational efforts, and notification laws. As long as any insecticide is sprayed, honeybees will be at risk. However, when the label instructions are followed and good communication exists among growers, applicators, and beekeepers, the threat to these pollinators is minimized. Therefore, the statements regarding the ineffectiveness of the label language should be removed.

6. Additionally, changes to the current label warning are not likely to reduce bee kills. Also, the suggested changes are not clear. For example, the statement "likely to be present" is open to a variety of interpretations. Elf Atochem is willing to add the statement concerning the additional requirements of state or tribal pesticide agencies.

VII. CONCLUSION

Cheminova appreciates the opportunity to offer these comments and looks forward to working with EPA to resolve the many issues it has raised. Cheminova believes that consideration of its comments will reduce the Agency's concerns with regard to this compound and will lead to the conclusion that the draft EFED chapter overestimates the potential risks associated with the use of methyl parathion. Cheminova will submit more extensive comments during the 60-day period.

VIII. REFERENCES

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Confidential Attachment A

REPORT TITLE

Evaluation of the Environmental Fate and Effects Division's
Draft Reregistration Eligibility Decision Chapter for Methyl Parathion

DATA REQUIREMENTS

Not Applicable

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Confidential Attachment A

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA Section 10 has been removed to this confidential attachment, and is cited by cross-reference number in the body of the study.

Cross Reference Number 1

This cross reference number noted on a place-holder page is used in place of the following whole page at the indicated volume and page reference.

The deleted page is attached immediately behind this page.

PAGE	REASON FOR THE DELETION	FIFRA REFERENCE
17	Financial sales information on methyl parathion	Section 10